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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/754,226	01/09/2004	Michael Robert Forman	CVG-5614CON	8038

30452 7590 04/07/2005

EDWARDS LIFESCIENCES CORPORATION
ONE EDWARDS WAY
LEGAL DEPARTMENT
IRVINE, CA 92614

EXAMINER

FRISTOE JR, JOHN K

ART UNIT	PAPER NUMBER
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3751

DATE MAILED: 04/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

SP

Office Action Summary

Application No. 10/754,226		Applicant(s) FORMAN, MICHAEL ROBERT	
Examiner John K. Fristoe Jr.		Art Unit 3751	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 40-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 49 is/are allowed.
- 6) ☒ Claim(s) 40-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 1/9/2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/9/2004, 2/13/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statements filed 1/9/2004 and 6/28/2004 are acknowledged by the examiner.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 41-48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 41-48 depend from a previously canceled claim. It is impossible to determine the meets and bounds of these claims.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 40-43 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 5, 5, and 5 respectively, of U.S. Patent No. 6,685,672 in view of U.S. Pat. No. 6,575,932 (O'Brien et al.). Although

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the conflicting claims are not identical, they are not patentably distinct from each other because claims 1, 5, 5, and 5 of U.S. Pat. No. 6,685,672 in view of O'Brien et al.

“anticipate” Application claims 40-43, respectively. Accordingly, Application claims 40-43 are not patentably distinct from claims 1, 5, 5, and 5, respectively, of U.S. Pat. No. 6,685,672 in view of O'Brien et al.

Here Patent 6,685,672 claim 1 requires:

A catheter for delivering agents to a defined biological space in vivo comprising:

- A catheter shaft having a proximal end and a distal end;
- Marker bands on said catheter shaft;
- A first balloon proximal to said catheter shaft distal end;
- A second balloon proximal to said first balloon;
- A third balloon located proximal to said second balloon;
- A first agent delivery segment on said catheter shaft between said first balloon and said second balloon; and
- A second agent delivery segment on said catheter shaft between said second balloon and said third balloon.

While Application claim 40 requires:

A catheter comprising:

- A catheter shaft having a distal end having a shaft distal tip and a proximal end;
- A first balloon positioned on the shaft proximate to the shaft tip;
- A second balloon positioned on the shaft proximate to the first balloon;

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- A third balloon positioned on the shaft proximate to the second balloon;
- A first agent delivery segment having orifices formed therein positioned on the shaft between the first and second balloons;
- A second agent delivery segment having orifices formed therein positioned on the shaft between the second and third balloons; and
- A guidewire lumen formed within the shaft and in communication with a port formed on a proximal end of the catheter.

Following the rationale of *In re Goodman* cited in the preceding paragraph, where Applicant has once been granted a patent containing a claim for the specific or narrower invention, Applicant may not obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer. Note that since Application claim 40 is anticipated by claim 1 of Patent 6,685,672 and anticipation is the epitome of obviousness, then Application claim 40 is obvious over claim 1 of Patent 6,685,672.

In addition, Application claim 40 requires a shaft distal tip and a guidewire lumen. O'Brien teaches a catheter comprising multiple balloons (90 and 130), a distal tip (the right end of the catheter is figure 1A), and a guidewire lumen (155). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the catheter having multiple balloons of claim 1 of Patent 6,685,672 by having the catheter have a tip and a guidewire lumen as taught by O'Brien in order to guide the catheter to a specific location in the body more easily and for the catheter to have an enclosed tip so that it does not take on any fluid during the medical procedure.

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Similarly, claims 41-43 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5, 5, and 5, respectively, for the same reason set forth above.

Allowable Subject Matter

6. Claim 49 is allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John K. Fristoe Jr. whose telephone number is (571) 272-4926. The examiner can normally be reached on Monday-Friday, 7: 00 a.m-4: 30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine R. Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JKF



John K. Fristoe Jr.
Examiner
Art Unit 3751



EDWARD K. LOOK
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700

3/31/05